European Parliament
2024-2029

Plenary sitting

B10-0128/2024

16.10.2024

MOTION FOR A RESOLUTION

to wind up the debate on the statement by the Commission

pursuant to Rule 136(2) of the Rules of Procedure

on the urgent need to revise the Medical Devices Regulation
(2024/2849(RSP))

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on behalf of the ECR Group

B10-0128/2024

European Parliament resolution on the urgent need to revise the Medical Devices Regulation
(2024/2849(RSP))

The European Parliament,

– having regard to Article 168 of the Treaty on the Functioning of the European Union, which recognises the EU's competence in the field of public health,

– having regard to Article 114 of the Treaty on the Functioning of the European Union,

– having regard to Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices, amending Directive 2001/83/EC, Regulation (EC) No 178/2002 and Regulation (EC) No 1223/2009 and repealing Council Directives 90/385/EEC and 93/42/EEC[1] (MDR),

– having regard to Regulation (EU) 2017/746 of the European Parliament and of the Council of 5 April 2017 on *in vitro* diagnostic medical devices and repealing Directive 98/79/EC and Commission Decision 2010/227/EU[2] (IVDR),

– having regard to Regulation (EU) 2024/1860 of the European Parliament and of the Council of 13 June 2024 amending Regulations (EU) 2017/745 and (EU) 2017/746 as regards a gradual roll-out of Eudamed, the obligation to inform in the event of interruption or cessation of supply and the transitional provisions applicable to certain *in vitro* diagnostic medical devices[3],

– having regard to its position at first reading of 16 February 2023 on the proposal for a regulation of the European Parliament and of the Council amending Regulations (EU) 2017/745 and (EU) 2017/746 as regards the transitional provisions for certain medical devices and *in vitro* diagnostic medical devices[4],

– having regard to the information note from several Member States on the miscellaneous item submitted to the Employment, Social Policy, Health and Consumer Affairs Council on 30 November 2023 concerning the implementation of the MDR and the IVDR,

– having regard to Regulation (EC) No 1907/2006 of the European Parliament and of the Council of 18 December 2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH), establishing a European Chemicals Agency, amending Directive 1999/45/EC and repealing Council Regulation (EEC) No 793/93 and Commission Regulation (EC) No 1488/94 as well as Council Directive 76/769/EEC and Commission Directives 91/155/EEC, 93/67/EEC, 93/105/EC and 2000/21/EC[5],

[1] OJ L 117, 5.5.2017, p. 1, ELI: http://data.europa.eu/eli/reg/2017/745/oj.
[2] OJ L 117, 5.5.2017, p. 176, ELI: http://data.europa.eu/eli/reg/2017/746/oj.
[3] OJ L, 2024/1860, 9.7.2024, ELI: http://data.europa.eu/eli/reg/2024/1860/oj.
[4] Texts adopted, P9_TA(2023)0052.
[5] OJ L 396, 30.12.2006, p. 1, ELI: http://data.europa.eu/eli/reg/2006/1907/oj.

– having regard to the Commission proposal of 3 May 2022 for a regulation of the European Parliament and of the Council on the European Health Data Space (COM(2022)0197),

– having regard to the Pharmaceutical Strategy for Europe, adopted by the Commission on 25 November 2020 (COM(2020)0761),

– having regard to the statement by the Commission of 9 October 2024 on the urgent need to revise the Medical Devices Regulation,

– having regard to Rule 136(2) of its Rules of Procedure,

A. whereas medical devices play a crucial role in public health by ensuring the effective diagnosis, treatment and monitoring of patients and users;

B. whereas the MDR was intended to improve the safety and performance of medical devices in Europe; whereas the requirements imposed on the notified bodies responsible for certification have led to a drastic reduction in the number and availability of notified bodies, even though they play a critical role in the market access process for medical devices;

C. whereas problems relating to the implementation of the MDR and delays in its application have caused difficulties for the healthcare sector and for the businesses concerned, leading to shortages, in particular for the hospital market and the paediatric sector;

D. whereas numerous stakeholders, including healthcare professionals, industry representatives and patients, have reported shortages, delays in the authorisation of medical devices, and barriers to innovation;

E. whereas the increase in regulatory requirements has led to additional costs for manufacturers, particularly small and medium-sized enterprises (SMEs), thereby reducing their ability to innovate and remain competitive;

F. whereas the COVID-19 pandemic had a major impact on the supply and use of medical devices in the Member States, whereas it highlighted the fragility of the supply of essential medical devices and emphasised the need to guarantee a robust and diversified supply chain by maintaining or restoring design, innovation and production capacities in the EU;

G. whereas delays in obtaining or renewing CE marking for medical devices could lead to shortages in hospitals and for patients requiring urgent treatment;

H. whereas innovative, safe and effective medical devices are essential for guaranteeing the quality of patient care and supporting the resilience of healthcare systems;

I. whereas certain provisions of the Green Deal could affect the availability of certain medical devices, in particular those containing per- and polyfluoroalkyl substances;

J. whereas the ‘one substance, one assessment’ principle could help to improve the safety

of medical devices by making it possible to judge whether a particular substance should be authorised on the basis of the criticality of the medical device in which it is used;

K. whereas the EU lacks skilled independent experts who are able to carry out certification audits for notified bodies;

L. whereas, as a result of the lack of certification timelines that should be binding for notified bodies and for manufacturers, these parties and various other stakeholders have reported difficulties in planning their activities, and this causes shortages and jeopardises the availability of innovative products, thus penalising patients;

M. whereas the innovative regulatory framework referring to substance-based medical devices, which was introduced by the MDR, is intended to encourage the development of therapies that act through non-pharmacological, non-immunological and non-metabolic means; whereas guidelines and decisions issued by national authorities set limits that classify products falling within the scope of the MDR under other regulatory categories, which goes against the EU legislator's aim of fostering therapeutic innovation;

N. whereas the EUDAMED database was supposed to be operational by May 2022, but delays have resulted in a phased roll-out and only partial deployment;

O. whereas the *in vitro* medical devices sector faces particular challenges, given that far more effort is required to achieve compliance under the IVDR than under the previous directive;

P. whereas e-health applications of which the purpose corresponds to the definition of medical devices are not currently certified, and therefore potentially endanger users' health data;

1. Expresses its deep concern about the negative effects of delays in the implementation of the MDR, in particular on innovation, on the competitiveness of SMEs and certification companies, and on patient access to essential medical devices;

2. Calls on the Commission to urgently revise the MDR in order to simplify approval procedures, in particular for low-risk devices and technological innovations, reduce the administrative burden, and lessen unmet medical needs;

3. Invites the Commission to introduce a temporary mechanism, complementary to the amendments introduced by Regulation (EU) 2024/1860, to enable the appropriate extension of existing certifications for medical devices pending the full implementation of the new certification framework, and asks that the Commission improve and promote the streamlining of the certification process for devices in order to prevent critical shortages and ensure safe access to medical devices for patients;

4. Stresses the importance of striking a balance between rigorous safety requirements and rapid, efficient approval processes, particularly for innovative devices with significant benefits for users;

5. Calls for the introduction of specific support measures for SMEs, including technical

and financial assistance to help them comply with the new regulatory requirements without undermining their competitiveness;

6. Calls for specific measures to be taken to strengthen, maintain and adapt the capacity of notified bodies to handle innovation;

7. Suggests that consideration be given to a fast-track procedure for the approval of vital medical devices in times of health crisis, noting that it would be appropriate to focus on the shortages of medical devices and *in vitro* diagnostic medical devices created by the transition to the MDR and the IVDR;

8. Stresses the need to protect health data collected by e-health applications by expressly including these applications in the scope of the revised MDR and by laying down appropriate provisions on them;

9. Calls on the Commission and the Member States to strengthen the resilience of medical device supply chains, including through diversified production and better European coordination, in order to avoid shortages;

10. Stresses the importance of transparency in the certification process for medical devices and invites the Commission to publish regular progress reports on the implementation of the MDR;

11. Stresses the need for predictable timelines and costs for the assessment of technical documentation, and thus the need to adopt binding legislative measures requiring notified bodies and manufacturers to respect their mutual obligations so that certification can be obtained within the agreed time frame;

12. Emphasises that it is important for the Commission and other regulatory bodies to promote the correct classification of products, thus embracing the scope for innovation provided by EU legislator and to ensure that there are no obstacles to the development of innovative therapies originating from the medical device sector;

13. Points out that EUDAMED's transparency may be exploited in order to interfere with and undermine the EU and the Member States; considers, given this, that the information made available should be tailored to the audience;

14. Calls on the Commission to submit to Parliament, without delay, a detailed report on shortages directly or indirectly attributable to the implementation of the MDR, listing the devices concerned and the health consequences for patients and users;

15 Calls for increased collaboration between the EU, national regulatory agencies and healthcare stakeholders to ensure harmonised implementation of the MDR;

16. Instructs its President to forward this resolution to the Council, the Commission and the governments and parliaments of the Member States.